OCT 2 1 2005

K052349

6.0 510(K) SUMMARY

The Avante LED curing light performs the same intended function as its predicate device, Versalux (reference K010133). Both devices are both used as a light activation system for dental restorative resins.

The physical features of the Avante LED curing light provide the dentist with a compact shape and cordless design to facilitate ease of use while using standard light emitting diode technology for optimum curing functions. The Avante LED curing light provides minimum output of 1,000 MW/cm2 which results in typical curing times of 10 seconds for most composite materials. Peak output is measured at 470nm. Curing time can be set between 1- 40 seconds for greater versatility in individual applications.

Accessories include the Avante light guides which are available in four diameters to accommodate dentist preference and use.

The effective portability of the Avante LED curing light is maintained through use of a charging light which is incorporated into the device stand. Included as well in the charging light is a radiometer display to verify proper light output. Lithium-ion batteries power the device and provide 45 minutes on average between charging times.

A review for safety and effectiveness was performed and found not to have been affected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Mr. Greg Moreau
Quality Systems
Pentron Clinical Technologies
68-70 north Plains Industrial Road
Wallingford, Connecticut 06492

Re: K052349
Trade/Device Name: AVANTE LED CURING UNIT, MODEL N44
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: II
Product Code: EBZ
Dated: September 29, 2005
Received: October 3, 2005

Dear Mr. Moreau:

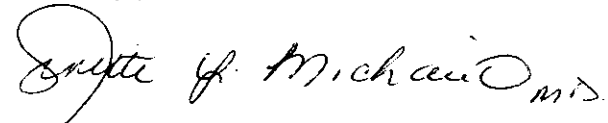
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052349

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN):

DEVICE NAME: Avante LED

INDICATION FOR USE:

The Avante LED curing light is used as a light activation system for dental restorative resins.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) **OR** **Over –The-Counter-Use** _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices